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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,311	09/18/2003	Bassil I. Dahiyat	A-67229-12	8879

7590 07/12/2005

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EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/666,311

Applicant(s)

DAHIYAT ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Amendment and response filed 04/25/2005 are acknowledged.

Claim 9 is added. Claims 4-9 are pending.

2. During the subsequent interview conducted on 05/24/2005, after an extensive discussion of utility issues, it was agreed that applicant would further consider amendments to the claim and specification to resolve the issues of the utility of invention, and therefore, the next Office action would defer addressing these issues until the next applicant's response.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. (new) Claim 4: The claim is directed to method for generating a secondary library; however the method results in generating a tertiary, not secondary, library. Please clarify.

B (new). Claim 4d): the phrase "ranking secondary library" is not clear. Specification does not discuss what kind of "ranking" is applied to the secondary library (ranking is discussed with respect to "primary libraries").

C (new) Claim 4d): Further, claim 4d is unclear with respect to "eliminating at least one unfavorable sequence from secondary library". Specification does not discuss what are the criteria for "unfavorable " sequences and thus it is not clear what is encompassed by this method step.

***Claim Rejections - 35 U.S.C. § 101/ 112-1***

4. Claims 4-9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

As stated above, the discussion of this rejection is deferred until the next applicant' response.

***Claim Rejections - 35 USC § 102 and 103.***

5. Rejections of claims 4-8 under 35 U.S.C. 103 over Srinivasan et al are withdrawn in view of applicant's arguments.

6. Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Topham et al. (J. Mol. Biol., 229, 194-220, 1993)

The claims are drawn to method for generating a library of scaffold protein variants comprising:

- a) generating library of sequences using an alignment program;
- b) generating a probability distribution of variant amino acid residues in a plurality of positions;
- c) combining residues from said probability distribution to generate secondary library;
- d) ranking the secondary library to generate tertiary library
- e) synthesizing protein variants from tertiary library of scaffold protein variants.

Topham et al teach method of modeling protein variants by comparing proteins in a protein families, calculating frequencies of occurrence and probabilities for selected residues, and applying smoothing and ranking functions. The method includes the steps of :

- a) generating library of sequences using an alignment program – see abstract, p. 195, last paragraph , p. 196 , section (a) and last paragraph ;
- b,c) generating a probability distribution of variant amino acid residues in a plurality of positions and thus generating secondary library - see p. 196, last paragraph, p. 200, left column;
- d) ranking the secondary library by applying two smoothing entropy-driven weighting functions – see , p. 200, section (d)

Topham reference does not teach synthesizing protein variants from the obtained library of protein variants. However, it would be *prima facie* obvious to one skilled in the art that the desirable end stage of any protein modeling is synthesis of proteins of interest; thus an artisan would be motivated to synthesize optimized protein variants obtained by method of Topham. Further, selection of PCR method to synthesize proteins would be obvious to an artisan as it is one of the main methods of protein

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synthesis, and selection of particular parameters of PCR would be obvious to an artisan as a part of routine selection of optimal parameters.

### ***Double Patenting***

7. Claims 4-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-8 of U.S. Patent No. 6,403,312. The rejection is maintained for the reasons of record as applied for claims 4-8.

Applicant argues that the claims, not specification are considered in a double patenting and examiner's reference to specification is improper. Examiner disagrees. The rejection addressed the claims of '312 patent. As to the reference to specification, claim 4a is directed to "providing a first library computationally rank-ordered list of scaffold protein primary variants". Specification, col. 8, lines 9-15, clearly identifies use of alignment software for providing a first library computationally rank-ordered list of scaffold protein primary variants: "sequence and/or structural alignment programs can be used to generate primary libraries."

As instructed by MPEP (section 804.1):

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.

The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970).

In the instant case, the rejection cites portions of specification which provide support for the claim language.

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8. Claims 4-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-29 of copending Application No. 09/927790.

This is a provisional obviousness-type double patenting rejection.

Applicant submits that this rejection will be addressed after the claim scope in this and the co-pending application is re-evaluated.

### **Conclusion**

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, PhD, can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.

Primary Examiner

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